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RU 486: A LESSON IN RESPONSIBILITY AND ACCOUNTABILITY

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The current controversy surrounding the introduction of the French abortifacient, RU 486, into the U.S. should not be simplistically characterized as the FDA's failure to admit a promising new drug for women. Rather, the furious debate over this drug derives from an entire systemic failure – a failure to take responsibility. A failure by the medical and scientific community to fully and objectively assess the known and unknown dangers to women's health and safety. A failure by purveyors of information in the manipulation of theoretical and highly preliminary evidence regarding potential uses for this drug in the treatment of several tragic diseases. A failure of the Food and Drug Agency itself to make clear both to itself and to the public its policies, and its justifications for its policies. A failure of Congress to providing leadership and guidance from a democratic majority on this issue which affects our entire country. And, most of all, a failure of the American public to truthfully scrutinize the choices we are making for ourselves and to take responsibility for their implications and consequences. Many of us would rather place the burden on deciding the correct course of action solely on the manufacturer of the drug. RU486 is merely another tool which may be used to bring life or death, suffering or its alleviation in the hands of men and women. In order to decide how to use that tool wisely, or to abstain from using it all, we must look closely at facts and the nature of what is at stake, and each of us take responsibility for arriving at reasoned solutions.

L The FDA must scrutinize the safety and efficacy claims of RU486 as the first step in assessing its

use as an abortifacient within the U.S.

In order to market a new drug in the U.S., a manufacturer must first demonstrate that the drug is effective and safe for its intended use. Foreign clinical trials may be acceptable for this purpose, as long as the data generated meet the same standards as studies performed in the U.S. Part of the FDA's oversight involves the minimization of bias in the testing of a new drug. Therefore, manufacturers are generally expected to utilize independent medical experts to test their compounds, thereby ensuring objectivity and neutrality in the generation and analysis of study data.

The synthetic drug, RU-486 (mifepristone) was developed in 1982 by French scientist Dr. Etienne-Emile Baulieu, consultant to Roussel Uclaf (a subsidiary of the parent German company, Hoechst AG). The drug moved quickly into clinical trials in women, after only 17 months of animal research. Early clinical trials included small

numbers of women, ranging from 35 to 271 women, and took place in Geneva, France, Sweden, Australia, Holland, the U.S., England, Finland and China. However, the largest studies supporting its use in Europe were conducted by Roussel Uclaf or by entities affiliated with the French company. (Klein at 12, 1991) In 1988, when Roussel decided to suspend distribution of RU 486, the French government, which owns 36% of Roussel Uclaf, ordered the company to place the drug back on the market. The justification given for its order was that RU 486 was the moral property of women, while making no reference to its safety or efficacy. (Nau and Nouchi, 1988)

The reported success rates of RU486 (if of women in administration 486 resulted in complete termination of pregnancy without the need for surgical intervention) was found to be between 60 (Herrmann, 1982) and 70% (Kovacs, 1984). In order to improve the drug's success rate, RU 486 began to be administered in combination with another class of compounds known as *prostaglandins* (PGs), which induce uterine contractions, thereby facilitating the expulsion of the embryo from the body. The addition of a prostaglandin, such as misopristol (Cytotec) and gemeprost, improved the success rate to above 90%, and remains the current practice. However the addition of this second powerful class of compounds has raised important considerations regarding the safety of this drug combination.

It is often true, that the more powerful a drug in achieving its desired purposes, the greater its potential for producing undesired outcomes. In considering the safety risk of a new drug, the FDA must consider the action of the drug upon the body (more specifically, the manner in which the drug is absorbed, distributed in body tissue, metabolized and excreted) and the influence of other chemicals on its action when taken in combination. Moreover, what is not known may be just as important as what is known about a drug in an assessment of its safety. The perceived desirability of a new drug should not be allowed to undercut in way close and objective scrutiny of the complications, adverse events and contraindications and significant unanswered questions, as this is an essential part of the critical judgment the agency must make in weighing the risks and benefits of a drug's use in the U. S.

The action of RU 486 and its interaction with PG is complex and far from fully understood. RU 486 is theorized to induce abortion by blocking the action of the hormone, progesterone, in the uterus which is needed to maintain pregnancy. Progesterone is a steroid hormone with diverse effects in the reproductive system, the breasts and the central nervous system. Because of its ability to bind to the progesterone receptor, RU 486 may have untold effects beyond the uterus, given that is taken systemically. RU 486 is also a glucocorticoid blocker, in which case it would also affect the adrenal glands. Increased susceptibility to infection is a common result of adrenal

insufficiency, raising the question of whether the drug's antiglucocorticoid effect may implicate a woman's recovery in the event of the need for curettage after a failed RU 486-induced abortion. Because no sophisticated pharmacokinetic studies have been done, the drug's half-life of RU 486 also remains undefined, in which case the question of how long its systemic effects may last remains unknown. Furthermore, because no adequate dose response studies appear to have been conducted (generally done in the second phase of American trials), neither is the optimal dosing or therapeutic ratio as yet known. Rather, arbitrary doses have been selected which achieve results effective in inducing abortion; however, what does appear certain at this point is that the current 600 mg dose is in excess of what is actually required. (JoM, 196)

While the addition of POs clearly improve the efficacy of RU 486, they also contribute significantly to concerns for side-effects. PGs are a class of highly active hormone-like compounds whose understood limits of safe usage is still in its infancy. They have marked cardiovascular actions and are theorized to be the major cause of the cardiovascular events and other major noxious side effects experienced with the combined RU486/PG treatment. Immune suppression is a common ethical compromise made in patients treated with PGs for cancer and tissue transplant. To date, however, no known studies have been done researching the potential of RU486 and PG. taken in combination, to weaken the immune defense against malignancy and infection, nor any other of the potential adverse short or long-term effects resulting from their interaction. Furthermore, within the U.S., no prostaglandin has been approved for abortion purposes, raising separate safety, labeling and marketing issues for the use of this combination within the U.S., should NDAs be submitted.

Significant adverse reactions and complications have been experienced in studies performed with the RU486/PG combination. Published reports all speak of pain, severe cramping, nausea, vomiting, and bleeding among study participants. Incomplete abortions may occur between 2% (Gao, 1988) and 13% (Rodger and Baird, 1989), which requires a woman to undergo surgical abortion in order to avoid infection. Severe and prolonged bleeding, lasting from one to 44 days (mean duration 8-10 days) is reported, with some women requiring transfusions and curettage. (idJ) Pain is also the common experience with this procedure; the drug's manufacturer in the U.K.. has acknowledged that 30% of the women required narcotics for their pain. (Roussel Laboratories, 1991).

RU 486/PG has caused one death, in 1989, and a number of serious cardiovascular side effects, two of which were life-threatening. (New York Times, 1991) After having reviewed the data of 30,000 women, an international group of scientists and doctors in Paris urged the Ministry of Health to immediately suppress the distribution and

use of RU 486 because of the grave secondary effects of chemical abortion which is falsely seen as an alternative to surgical abortion. (Kami, at 9, 1990) As a result of these events, the company circulated to all clinics strict guidelines, adding asthma, cardiovascular risk facts, e.g. smoking, obesity, elevated serum lipids, diabetes and high blood pressure to the list of contraindications, and excluding women over the age of **35**. (Le Quotidien De Medicin, 1990). Women with a number of other potential contraindications have been excluded from clinical studies. These include menstrual irregularities (Couzninet, 1986); women with fibroids or endometriosis (Li, 1988); cervical incompetence (Grimes, 1988) and previous abortion history (Grimes, 1990); use of oral contraceptives within three months of conception (Swahn and Bygdeman, 1989). Therefore, unknown potential for injury to women exists by RU 486 if they have an undetected medical condition, or because such women with these medical histories have not been adequately represented in the testing of this drug.

A final consideration for the safe use of RU 486 is the regimen of drugs which is used to accomplish chemical abortion, refereed to by some as the Chemical Cocktail. (Klein at 486, 1991) As noted above, RU 486 must be taken with a PG in order to achieve acceptable levels of efficacy. Added to this is the common use of narcotics and other analgesics for the pain experienced by women during this process. Furthermore, antibiotics for potential infection due to incomplete abortions, oral contraceptives to stop bleeding. and anti-diarrhea and anti-nausea medications for gastro-intestinal side-effects are often given to women. Potential adverse drug interactions for these mixtures, however, have not been closely studied.

Because of legitimate safety concerns, chemical abortions induced by the RU 486/PG combination are currently given under strict medical supervision in Europe. The French government, the manufacturer, and physicians administering the drug regimen throughout Europe consistently affirm that to maintain safety, extremely close medical supervisor is required. This concern for women's safety is echoed as well here in U.S. where the American Medical Association has asserted that RU 486 poses a severe risk to patients unless administered as part of a complete treatment plan under the supervision of a physical (testimony of Dr. P. John Seward of the American Medical Association before the U.S. House of Rep. Subcommittee on Regulation, Business Opportunities, and Energy, Nov. 9, 1990). A woman wishing to utilize this method must make a total of four visits to an authorized clinic or hospital equipped with an electrocardiogram, cardiorespirator and coronary spasm medication. (Muhi at 321, 1993) On the first visit, a woman discusses this option with a physician and submits to a physical examination which includes a pelvic exam a pregnancy test, and possibly a vaginal ultrasonogram to determine if she is within the

42 day window in which she may take the drug. A woman must then return to the clinic or hospital after at least a 24 hour waiting period, at which time she takes the RU 486 in the presence of a nurse or doctor. On the third visit, two days later, the woman is administered PG either by injection or by vaginal suppository. She must lie prone and have her blood pressure checked on a regular basis. Expulsion of the embryo may occur while at the clinic, however, many women must wait days to weeks before her body voids the embryo. Therefore, the woman must return a fourth time for a physical examination to make sure abortion is complete. If not, conventional abortion must be performed..

II. Manipulation and mischaracterization of facts concerning the use and benefits of RU 486 to gain public support for its entry into the U.S.

Probably the most compelling claim made on behalf of RU 486 is that it will make the obtaining of an abortion a more private and convenient event. However, it is clear that obtaining a chemical abortion by the use of the RU 486/ PG drug regimen is neither simple nor private. Rather it is a complicated, multi-step process involving pain, heavy bleeding, and other noxious side-effects. Neither will it relieve a woman of invasive medical treatment, given the numerous examinations and tests to which she must submit. Nor will it increase her opportunity for autonomy and self-control in the midst of her abortion. Rather, it will increase the decree of medical intervention and control over her by increasing the amount of visits she must make to a health facility, the number of medications she must take (and her exposure to risks of adverse drug interactions), and the length of time she must be monitored and treated for a successful abortion.

In assessing the desirability of RU 486 as an alternative to the current form of abortion, the drug regimen should be compared directly to currently used forms of abortion. Although a claimed advantage of RU486 is that it avoids the risks of surgery and anesthesia, in fact, surgery and general anesthetic is not administered with many conventional abortions (i.e., vacuum aspiration in which a local is given). Conventional abortions are 99% percent effective, require 1-2 medical visits, have fewer contraindications and complications, and can be performed over a wider range of time post-conception. (Klein at 50, 1991) It has been acknowledged by Edouard Sakiz~ chairman of Roussel Uclaf, that, As abortifacient procedures go, RU 486 is not at all easy to use. In fact it is much more complex than the technique of vacuum extraction. True, no anesthetic is required. But a woman who wants to end her pregnancy has to 'live with' her abortion for at least a week using this technique. It's an appalling psychological ordeal. (Boston Herald, Jul. 31, 1992) Attesting to the reality of this statement is a study published last year in

France which showed that among women who had received the RU 486/PG combination regimen, three times as many were unsatisfied with this regimen as with curettage offered under either local or general anesthesia (Institute of Medicine at 184, 1993)

Because of the chemical nature of RU 486, as both a chemical blocker of sex hormones and glucocorticoids, has understandably lead the scientific community to hypothesize about potential uses of this drug as a research and therapeutic tool in areas other than abortion. However, in order to accurately assess the known benefits of this drug it is necessary to look closely at the evidence underpinning claims of effectiveness for the treatment of other conditions. In their zeal to appeal to their respective audiences, the media, and certain sectors of the medical and political community have acted irresponsibly in holding out RU 486 as more than medical science knows it to be. This has the affect of playing to people's hopes and perhaps desperate situations, while failing to form a solid foundation for rationale and well-balanced decisions regarding the use of this drug.

Claims for uses other than abortion include (most notably) pre and post-coital oral contraception, menses regulation, cervical dilation, endometriosis, breast cancer, meningioma and Cushings Disease. However, at present, these claims are preliminary at best in that they are based only upon theoretical projections, sparse animal data and small, uncontrolled clinical studies. None have been sufficiently promising for the company to seek licenses for any indication other than abortion (the only indication for which significant evidence of efficacy or safety has been generated).

As a morning after pill or menstrual regulator, RU 486 is not generally considered because it causes a womans ovulatory and menstrual cycles to become unlinked. Furthermore, the relative value of RU 486 for contraception cannot even be judged until the long-term effects of continuous administration is known, which is clearly not known.

Several studies in animals showed that RU486 have raised interest for the use of this compound in controlling estrogen-dependent conditions such as endometriosis and breast cancer, however, A very limited body of data shows mixed and unclear results. A study in monkeys reveals that higher doses of the antiprogesterin both elevates the concentration and deactivates the estrogen receptor (Hodgen, 1991), and in rats, no regression of endometriosis was observed when treated with RU 486. (Tjaden, 1993) A study in six women found no significant change in the extent of the disease when treated for 3 months, while longer treatment (6 months) in 9 women showed significant improvement in 8 of 9 women. (unpublished observation by Samuel Yen at Univ. of Cal.).

Despite hopes to the contrary, the clinical activity of antiprogestins, such as RU 486, in breast cancer patients is, in reality sparse and clinically unimpressive. Data on only 11 post-menopausal patients treated with RU 486 have been published, in which regression was reported in no patients, while delayed toxicity's (weight loss, fatigue, anorexia, nausea, malaise, somnolence and one grand mal seizure) were experienced. (Michna, 1992). Further complicating the picture is a study conducted last year in the University of Wisconsin Cancer Center, which found that RU 486 actually *stimulated* the growth of human breast cancer cells in vitro at a concentration found in women taking RU 486. (Jeng, 1993) Therefore, RU 486 appears to have both estrogen inhibitory and stimulatory activity which may call into question its use as a treatment for estrogen-driven breast cancer.

Only two small studies have been performed with RU486 in the treatment of meningiomas (rare inoperable brain tumors). The first involved 14 patients for periods ranging from 2 to 31 months, in which 5 patients showed reduced tumor measurement, with relatively mild side-effects. (Grunberg, 1991) In the second, of 10 patients receiving RU 486, control of tumor growth was seen in six patients, while progression of tumor growth occurred in four patients. (Lamberts, 1992) While encouraging, the clinical importance of these observations in patients having a disease with a highly variable natural history clearly remains to be defined. [see endnotes for brief discussion of Cushing's Disease]

III. **The Development of a National Policy regarding RU 486 - the Responsibility of the FDA and Congress.**

A. The FDA Import Alert of 1988 banning RU 486 from Importation for Personal Use.

In light of the safety issues and unanswered questions highlighted above, the FDA had sound scientific basis for concluding RU486 represents a significant health risk, and thus banning its import for personal use. The FDA has more to think about than one isolated woman who may bring the drug into the country under the best of circumstances. In developing its import alert policy, the FDA must envision the risks engendered in the drug's average expected use and weigh this against the benefits hoped to be achieved by permitting its importation. A strict and fairly elaborate medical protocol is strictly required for its safe and effective use in Europe. Many questions critical to the health and well-being of women remain unanswered regarding RU 486, such as its full impact on the reproductive systems and other organ systems, its long-term effects on a woman's subsequent fertility, and the dangers involved in its concomitant use with other medications, to mention a few. RU 486 carries with it an extensive list of contraindications for conditions relatively common and often undiagnosed and untreated within the

U.S. female population, due to lack inadequate health care or simple ignorance. None of the PG's used in combination with RU 486 is approved in this country for abortion. Further complicating the medical considerations are the societal issues. The danger of the current atmosphere of political and ideological posturing is that the misperceptions and mischaracterizations propagated regarding the drug are more likely to contribute to its misuse, thereby increasing the risks of its use. Given the fact that once in the country, the FDA retains little ability to regulate and safeguard its use, the agency is left with little choice but to ban its import for all but research purposes.

In weighing the risks and benefits of permitting the entry of RU 486 for personal use, the FDA must bear in mind all its intended uses. The most common reason for importing RU 486 is likely to be for terminating pregnancy, a use for which a safe and effective method already exists in this country. However, demand for RU 486 also exists for deadly diseases treatable only a few drastic means, most notably breast cancer and a rare form of brain tumor (meningiomas). Here, again, a reasoned assessment of the facts is critical to the proper development of FDA policy. As noted above, the scientific data simply does not support, as yet, the conclusion that RU 486 is a viable cure for breast cancer; and one in vitro study raises questions as to whether it may stimulate the growth of cancer cells. While the medical case for meningiomas is a bit stronger, further clinical study is clearly needed before any firm conclusions can be drawn. A further consideration is whether by permitting the importation of RU 486 for these experimental personal uses, patients forego other treatments, such as surgery or chemotherapy, for the promise of a more convenient cure', thereby allowing their medical status to worsen. What the FDA must ask itself is whether the strength of the scientific data, in terms of potential benefits to cancer (and other) patients, outweighs the risks posed by the use of RU 486 for the purposes it is likely to be imported. Given the known and unknown dangers, when taken alone, or with PG for abortion, as well as the weakness of the scientific data for its proposed benefits in other indications, the FDA was reasonable in considering the importation RU 486 for personal use to pose an unreasonable risk to the public. However, rather than blindly maintain a policy in the face of evolving medical insight, the FDA should consider specific exemptions from its general import alert when scientific and medical data justify doing so, as, potentially, in the case of treating inoperable meningiomas.

Where the FDA has most notably failed in its policy, however, is in that it promulgated rules having important public consequences without conducted an investigation into the medical and ethical considerations and without explicitly communicating the justifications for its policy. Neither has it provided opportunity for public comment either before or since the promulgation of its import rule. Regardless of whether the agency had authority

articulated judgment call, explicitly stating the reasons and justifications for the agency's actions, pursuant to investigative proceedings giving opportunity for comment from the public. This approach would have facilitated the flow of information needed to dispel many of misperceptions regarding RU 486 currently held by the public, and would have maintained the agency's legitimacy in reaching a controversial policy decision, *even if it was the wrong in its decision* (strangely enough Americans seem to have more respect for a potentially wrong decision made openly and explicitly, than for a potentially right decision made in a questionable manner). However, instead the agency relied on letters to senators and testimony in Senate hearings to clarify its position. This has created the appearance of the agency as merely covering up a purely politically-motivated decision post hoc, and has permitted the political and ideological grandstanding. and public misperceptions to continue to undermine rationale consideration of the issues surrounding the introduction of this drug. An administrative agency comes closest to illegitimacy when it acts in non-compliance with its own rules and fails spell out clearly what it is doing; and by doing so fails to take full responsibility for its important and controversial judgments. The FDA may not have purposefully set out to do this, but by acting in the manner in which, it accomplished as much.

Soon after entering the oval office, President Clinton instructed the FDA to revoke its exclusion of RU 486 if sufficient evidence does not exist warranting its continued exclusion. Essentially, the FDA has been called upon to do what it should have done in the first place, to make itself accountable for its decisions which have intimately affected people. However, in meeting's the President's challenge to its current policy, the FDA must do two things. It must make a careful and objectively assessment the scientific and medical data regarding the risks and benefits of importing this drug. as well as the implications of the current misleading claims regarding its use. In doing so it should resist political influence to suppress valid concerns regarding its safety (by the left wing) or to exclude the drug for scientifically and ethically sound uses (by the right wing). Secondly, the agency must establish for itself a fundamental policy regarding the ethical implications of the use of RU 486, which it has thus far been able to escape doing no NDAs have been submitted its approval in this country. Only by doing these things will it ultimately be able to preserve its autonomy. legitimacy and the public faith it has striven so hard to maintain.

B. Developing a sound medical and ethical policy regarding the potential approval of RU 486

Until recently, Hoechst AG has been extremely reluctant to permit its subsidiary, Roussel Uclaf to make available RU 486 in the U.S. In 1992, Roussel Uclaf issued several required conditions before marketing the drug for abortion in any country.¹ Frequent allegations have been levied that FDA hostility towards the drug (as evidenced by its placement on import alert) is responsible for the company's unwillingness to pursue clinical testing and marketing of RU 486 within the U.S. However, numerous statements by the company belie the common assumption that political pressure or the FDA Import Alert has determined their decision. Rather, they cite their own internal policies and standards regarding study protocols, and the conditions explicitly laid down for their agreeing to commence clinical testing. Less frequently mentioned, however, is chairman Wolfgang Hilger's moral conviction that Hoechst should not market RU 486 and that commercialization of a drug facilitating abortion is against Hoechst's corporate credo. (Wall St. Journal, Feb 22, 1993) It is reasonable to assume that the company's desire to avoid boycotts, tort liability and political hassle play some role in the its reluctance to enter into the American market. However, respect for the private decision making of a company operating in the U.S. must be maintained. This is particularly true where moral convictions regarding the ethical use of its products combines with rational economic self-interest (although, it may be argued that moral convictions may have actually overshadowed economic considerations in Hoechst's decision, given the enormous profit which could have been made in this country). The American system of medical innovation is based in large part upon private initiative in research and development, in that the FD&C Act explicitly places responsibility for testing new drugs on the manufacturer who desires FDA approval. The FDA has no authority to require a company to investigate a new drug. however promising, nor can any citizen compel the FDA to undertake studies of a drug or to permit a drug to be made available for treatment. *See, e.g., DeVito v. HEM, Inc.*, 705 F.Supp. 1076 (MiD. Pa 1988) While the FDA should encourage applications for compassionate ThJDs for persons with these other indications who cannot be satisfactorily treated by available alternative methods, attempting to compel the licensing of RU 486 in the U.S. by its manufacturer, while lacking statutory mandate or authority to do so, would be an illegitimate use and expansion of the FDA's power.

Inevitably, however, at some point the future, the FDA will receive an application for RU486, or some other similar compound. The FDA will then have to face squarely the fundamental ethical issue of whether **to** permit the

i(1) Abortion is legal and accepted by society, as demonstrated by a statutory ruling on abortion. (2) The availability of PF and strictly controlled distribution and use of RU 486 would mimic that of France. (3) A representative, competent body makes written request for the drug.

marketing of this drug in this country, and the regulatory issues which would follow, such as its labeling and distribution. One may approach this from two perspectives. The first concludes that the agency will have came out its ethical duty to society by strictly scrutinizing the available data and mandating the full barrage of clinical trials necessary to establish its long as well as short-term safety and efficacy of the drug. Under this standard, the European data is not likely to answer all the agency's misgivings with regards to its use in abortion (given what is currently known), if the it conducts its duty with scientific purity and integrity. If it has learned anything from its experience with oral contraceptives and IUDs, where the long-term health risks to women should have been assessed *prior* to their approval, the agency will move forward with this latest reproductive drug very cautiously, and let politics be damned.

With regards to its approval for other uses for RU 486, the FDA should require the complete animal and clinical testing for each indication, given that the state of the scientific and medical data is clearly highly preliminary. Because of its potential for use in certain life threatening conditions, the review process should be expedited, but only to the extend that safety and efficacy is not compromised. However, at the point in which an Investigational New Drug applications may be sought, the FDA should allow the use of compassionate (or treatment) INDs for concomitant treatment of patients with serious diseases, for which RU 486 shows real promise, and for which no alternative treatments are available.

The second approach, however, calls for a more controversial ethical judgment. It postulates that the FDA possesses the discretion to decide on an ethical basis that certain goals are morally inappropriate for the U.S. government to permit or to pursue. An example of such a judgment, is the FDA policy prohibiting U.S. companies from distributing abroad drugs not approved in this country, but which the receiving country would find unobjectionable by their own standards of safety and efficacy. In this situation, the FDA is essentially saying that we, the U.S. government, are not going to permit you, a sovereign nation, to have a drug which you desire, but which feel may harm you. You may obtain the treatment through some other means, as we cannot control all your available choices. However, as a matter of ethical principle, we, as a government, will not permit ourselves to be the means by which you exercise your right of choice to your own potential detriment (realizing that the issue of detriment itself is also a judgment call). Similarly, it is my contention that the FDA has the right to refuse to act in a manner desired and legally permitted of others in the interest of protecting the potential life of the unborn. In reality, this is the central rationale of the FDA's refusal to approve the marketing of Thalidomide, even with proper labeling. The FDA made a ethical judgment that in

order to safeguard the life and health of the unborn, it was worth giving up the benefits potentially derived by the use of that drug.

The refusal to permit the marketing of drugs for abortion may appear to some a radical idea, but truly it is not in light of the FDA's mandate to protect life and health, rather than to assist in extinguishing it. The fact that the life it would protect is at such an early stage in its development when terminated does not change the analysis, because it is still life regardless of the labels that may be placed upon it. *Roe* and *Casey* make clear that the government may not affirmatively act to burden the abortion decision, for which current forms of abortion remain constitutionally protected for the present. However, neither case imposes a duty upon the government to assist in facilitating the termination of life. As noted in *Webster*, the government has the right to safeguard potential life by all constitutionally permissible means. I would like to suggest, however unpopular the suggestion, that the refusal by the FDA to approve RU 486 for the purpose of achieving chemical abortion in this country, is one of those means, fully justified by the undeniable safety hazards posed by this drug to the smallest members of our society.

It may then be asked, however, if the FDA is able to make such a value judgment to restrict the availability of a safe and effective drug in this setting, upon what principle may we be reassured that it will not do so in other settings, with possibly disagreeable results from the other point of view. Where ends the capricious discretion of the agency? The answer to this question is two-fold. Firstly, the issue of abortion is indeed unique (differing even from that of assisted suicide) in that it involves not just the wishes and safety of one individual, the mother, but also that of a second individual, the unborn child, who cannot give consent to the harm perpetrated against it. I would pose that this is where the FDA's mandate is most compelling. to ensure and protect the health and safety of the most vulnerable members of our society who will inevitably be harmed if the agency fails to take action. Secondly, the FDA is always accountable, ultimately, to a democratic majority of the public through Congress. If indeed it has acted so far afield of the collective conscience of our people by denying approval to this drug. it is realistically possible for our feelings to triumph over FDA policy should the consensus be strong.

In reality, given the current political climate I would expect that a decision by the FDA to disapprove RU 486 for abortion purposes would be likely be overturned by Congress. However, because this process would potentially achieve several important ends, I do not think it would be pointless or meaningless. Firstly, it will permit the FDA to carry out its essential mandate, that of protecting the public health and safety, with respect to the most vulnerable of our society, the unborn. Secondly, it will require Congress to shoulder its rightful duty in providing guidance to both the

agency and to the American public with respect to this extremely difficult and contentious moral and ethical issue, rather than simply permitting a few outspoken congresspersons and powerful interest groups (the medical community included), to control the nature and outcome of the debate. Lastly, by highlighting the true nature of this drug, the FDA would hopefully cause the American public to stop and realistically assess the true nature of our choices and to realize that with choice comes responsibility and the consequences of that freedom, which brings me to my final and most important point.

The question we must ask ourselves, in considering the proper outcome to this debate, and many others currently like **it**, is whether, in reality, greater technology truly is always represents progress. Or rather, has technology in cases such as these merely allowed us to abdicated our responsibilities for our poor choices, so that in turn we place unrealistic, and almost desperate demands upon technology, and the entities who produce it, to provide us only short-term and inferior solutions to our problems. The critical lesson to learned of RU 486 is that quick fixes are an illusion; they are no substitute for each of us coming fully to terms with the real consequences of in our decisions, behavior, and social interactions. Our poor self-discipline, thoughtlessness, and lack of basic human dignity, leave us wanting easy, painless and private solutions, while attempting to ameliorate, deny or absolve ourselves of the burdens accompanying our rights. This, in my mind, is what RU 486 is essentially about. Will this drug truly empower people to choose, or will it merely enable people to helplessly react; because, in truth, who would choose to undergo the physical and emotional ordeal of several trips to the hospital, to have someone peer and probe the intimate parts of your body and to cause you pain, bleeding and discomfort by giving you a powerful, and still rather mysterious chemical, so that you may flush yourself of a part of your being you wished your had never conceived in the first place.

What role the FDA should play in the development of an increasingly drug-driven society is at the crux of its current dilemma, for which I do not have the answers. My greater purpose in posing the above options and questions is not to provide detailed solutions, which would probably just distract the reader from the greater search for the acceptable answers. Rather, my real goal in writing this paper is to sharpen the reader's focus on the cold facts and realities, so that we as a society, and the FDA as an agency with a great deal of sway and discretion, may begin **to** grapple with the true nature of our choices; and thus that we may begin to exercise our precious right of choice wisely.

ENDNOTES

(1) Cushing's Disease: RU 486 has been used to treat Cushing's Disease in one study by Bertagna, who state that this compound should not be considered a routine alternative for the treatment of Cushing's Disease. (Bertagna, 1986)

As a similar report by Nieman concluded that it shows some effectiveness, but is not proven safe. (Nieman, 1985) According to Roussel Uclaf, RU 486 shows efficacy only in two very rare forms of Cushing's syndrome, which is itself a very rare disease. (Letter to Dr. E.H. Drew, Jan. 19, 1992)

(2) Personal Note: As a woman, I do not lack compassion and insight into the enormous personal and ethical burden involved in the abortion decision, and the issues surrounding the legal right to obtain one. Neither do I think that

acting in any way which seems to restrict this right is politically expedient. However, I argue this position as a matter of conviction, which in many ways is not unlike the basic judgment that Congress and the FDA must make on a regular basis.